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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,687	09/28/2000	David Wallach	WALLACH=25	7238
1444	7590	01/26/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/671,687	Applicant(s) WALLACH ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>Waf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,20-24,38-40 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,21-24,38-40 and 42-47 is/are rejected.
- 7) ☒ Claim(s) 3,20 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/26/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 12/13/2005 in which claims 2 and 38-39 were amended. Claims 2-3, 20-24, 38-40 and 42-48 are pending in the instant application.

Because the prior Office Action was FINAL, and because the instant Office Action raises new rejections that are not necessitated by amendment, the finality of the previous Office Action has been withdrawn in favor of the instant non-final Office Action.

Priority

As has already been stated on the record, foreign priority is a matter of Written Description; in other words, the full scope of a claim must be described in the priority document in order for the full scope of any given claim to be granted priority. Applicant has sought allowance of claims encompassing SEQ ID NO: 3, variants of SEQ ID NO: 3 with at least 90% identity to SEQ ID NO: 3 and fragments of SEQ ID NO: 3. Applicant's claims to priority as a continuation-in-part of US Patent Application Number 09/646,403, which is a national stage application of PCT/IL99/00158, as well as applicant's claim to

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priority of two foreign patent applications (IL126024 and IL134604) are also acknowledged.

US Application 09/646,403 and foreign priority document IL126024 disclose clone #10, a nucleotide sequence for a partial polypeptide later identified as instantly claimed SEQ ID NO: 3 (i.e., a fragment consisting of amino acids 548-949 of SEQ ID NO: 3). However, no clear support exists for the full length of SEQ ID NO: 3 or, based upon the maximum possible identity given the length of the disclosed fragment in the cited priority documents, any variants of SEQ ID with greater than 42% identity to SEQ ID NO: 3 (See the Office Actions mailed 10/1/2004 and 6/13/2005).

However, foreign priority document IL134604 does disclose SEQ ID NO: 3 in its entirety and this priority claim was perfected upon receipt of the foreign priority document on 3/29/2005. Therefore, in the instant case, claims encompassing more than the 548-949 amino acid fragment disclosed in IL126024 and US Application Number 09/646,403 are only granted priority to the foreign priority document IL134604, filed on 2/17/2000.

Claim Objections

Claims 38-29 are objected to because of the following informalities: Claim 38 recites " [a]n isolated protein in

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accordance with claim 2, wherein said protein or variant is each capable of binding to a component of the NF- κ B complex selected from the group consisting of IKAP, IKK-alpha, IKK-beta, IKK-gamma and NIK" in lines 1-5. Claim 38 is objected to because the NF- κ B complex components of the claim should be spelled out.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2, 38-40, 42-43 and 47 are rejected under 35 U.S.C. 102 (a) as being anticipated by Stratton (see Genbank submission of November 29, 1999). **This rejection is a new rejection not necessitated by Applicant's amendment.**

Applicant's invention is drawn to an isolated protein which is capable of binding to tumor necrosis factor receptor-associated 2 protein (TRAF2), said protein consisting of: (A) a protein comprising the amino acid sequence of SEQ ID NO: 3; or (B) a variant having an amino acid sequence that is at least 90%

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identical with SEQ ID NO: 3 wherein said protein or variant is each capable of binding to TRAF2.

Stratton teaches a nucleic acid encoding a human CYLD protein with >98% identity to SEQ ID NO: 3 of the instant application. Because the claims encompass variants of SEQ ID NO:3 having at least 90% identity with SEQ ID NO: 3, and because Applicant's priority only reaches to the instant filing date of 2/17/2000 for claims drawn to the entire length of SEQ ID NO: 3 and variants with at least 90% identity to SEQ ID NO: 3, Stratton's human CYLD gene reads on claims 2, 38, 39, 40, 42, 43 & 47.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2,4, 20 and 38 were rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al (DNA Research 5:355-364, December 1998; of record). Applicant's amendment of the claims is found remedial with regard to this rejection and this rejection is hereby withdrawn.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratton (see citation above) in view of Applicant's admission in the paper filed 9/23/2002 that it would be obvious for one of skill in the art to make antibodies to a protein that is known in the prior art. **This is a new rejection not necessitated by Applicant's amendment.**

Applicant's invention is drawn to a molecule having the binding portion of an antibody capable of binding to the isolated protein of claim 2. Applicant's invention is further drawn to such a molecule wherein the molecule is an antibody and wherein the molecule is a monoclonal antibody as well as a composition comprising a molecule having the binding portion of an antibody capable of binding to the isolated protein of claim 2 and a pharmaceutically acceptable excipient, diluent or auxiliary agent.

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Stratton teaches a nucleotide sequence encoding a polypeptide sequence that has greater than 98% identity to SEQ ID NO: 3. However, Stratton does not teach making antibodies to this polypeptide.

It would have been obvious to make antibodies to this polypeptide because Applicant concedes that such an endeavor is obvious (see for example, page 3, first full paragraph of Applicant's response filed September 23, 2002). Motivation to make the antibodies would be to immunopurify the protein or to block its activity, again, as per Applicant's admission (see for example, page 4, the bottom of the paragraph bridging pages 3-4 of Applicant's response filed September 23, 2004). Although claims 44-46 are directed to antibodies that specifically bind to SEQ ID NO: 3 (a polypeptide not anticipated by Stratton), it should be noted that antibodies that bind to portions of SEQ ID NO: 3 taught by Stratton (amino acids 1-86, 88-193, 195-280, 282-301, 305-342, and 344-949) will also bind to SEQ ID NO: 3. In other words, antibodies directed to amino acids 1-86 as disclosed by Stratton will necessarily bind to amino acids 1-86 of SEQ ID NO: 3 because of the 100% identity between the amino acid sequences. Furthermore, it is noted that since the polypeptide was known in the art, it would be obvious to make antibodies to this sequence (as per Applicant's admission)

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regardless of the functional limitation on the claimed protein, and these antibodies would necessarily bind to the full length SEQ ID NO: 3 and variants thereof that have identical sequences within the antibody-binding region.

Thus, absent evidence to the contrary, the artisan of ordinary skill in the art would have been expected to make antibodies that bound to SEQ ID NO: 3 (or portions and variants thereof), as set forth by Applicant's admission concerning the production of antibodies.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 and 44-46 were rejected in the previous Office Action under 35 U.S.C. 103(a) as being unpatentable over Nagase (of record) in view of Applicant's admission in the paper filed 9/23/2002 that it would be obvious for one of skill in the art to make antibodies to a protein that is known in the prior art. This rejection is withdrawn due to Applicant's amendment.

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Response to Arguments

Although a new rejection under 35 U.S.C. 103(a) has been made in this Office Action, Applicant's arguments to the previous rejection made under 35 U.S.C. 103(a) are addressed here to expedite prosecution.

Applicant argued that Nagase's disclosure of an open reading for a protein expressed in brain cannot be considered to be a "biological activity or function" as would be commonly understood or recognized in the art and that just because a protein exists in a human body or even in one tissue of the body does not mean the protein has a "known" biological activity or function that would motivate one of ordinary skill in the art to make antibodies thereto.

Such an argument is not applicable in the case of Stratton's Genbank submission because Stratton identifies the submission as the "Familial Cyldromatosis Gene" with a known function: tumour suppressor/recessive oncogene.

Allowable Subject Matter

Claims 3, 20 and 48 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

January 20, 2006



JAMES KETTER
PRIMARY EXAMINER